

Serial No. 10/672,009

Dkt.: P0022022.00

Filing Date: September 26, 2003

Title: SURGICAL CONNECTION APPARATUS AND METHODS

REMARKS

Reconsideration and withdrawal of the rejections of claims 1-33, in view of the remarks presented herein, is respectfully requested.

Claim 18 has been cancelled by way of this Amendment. Claims 1-17 and 19-40 are pending. Claims 34-40 have been withdrawn from consideration. Claims 17, 22, and 28 have been amended. The amendments to the claims are fully supported by the Specification as filed. No new matter is believed to be introduced by way of this amendment.

The 35 U.S.C. § 102(e) rejection of the claims

The Examiner rejected claims 1, 2, 6/1, 6/2, 7/1, 7/2, 8, 14/8, 15/8, 16/8, 17-28 and 30-33 under 35 U.S.C. § 102(b) as being anticipated by Edoga *et. al.* ("Edoga" U.S. Patent No. 7,335,212). As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

Independent Claim 1

Claim 1 provides in part, "a plurality of self-closing clips...and a plurality of barbs...said barbs being separate from said clips, which are ejectable from said support structure independently of said barbs". The Examiner asserts at Page 2 of the Office Action that straight wire segments 134 are the plurality of shape memory self-closing clips. Applicants respectfully disagree. At the outset, straight wire segments 134 are not disclosed as shape memory self-closing clips. Rather, straight wire segments 134 slide within passage 132 and through hooked staple guides 140. Edoga discloses "movement of the staple firing trigger 108 will cause the staple drivers 138 to engage the straight wire segments 134 and displace the straight wire segments into hooked staple guides 140 to form the circular staples" Col. 4 line 65 – Col. 5 line 1; see also Col. 6 lines 63-67. In other words, straight wire segments require some other structure (e.g. staple guides 140) in order to be "formed into ring-shaped staples" Col. 1 line 65.

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Furthermore, at Page 3 of the Office Action, the Examiner alleges that staple guides 140 are the plurality of barbs separate from the clips and slidably disposed in a second plurality of paths. First, staple guides 140 are not barbs, rather, they are disclosed as hooked staple guides. Even assuming *arguendo* that staple guides 140 are barbs, as Applicants noted above, Edoga discloses “movement of the staple firing trigger 108 will cause the staple drivers 138 to engage the straight wire segments 134 and displace the straight wire segments into hooked staple guides 140 to form the circular staples”. Thus it is readily apparent that the straight wire segments of Edoga are not separate from nor are they ejectable independently of the staple guides 140.

The claims depending from claim 1 include additional allowable subject matter and are allowable at least by virtue of their dependency from an allowable claim thus requiring no further comment at this time. Thus, it is respectfully submitted that claim 1 and the claims dependent thereon are not anticipated by Edoga. Withdrawal of the rejection is therefore proper and respectfully requested.

Independent Claim 17

The arguments above with respect to claim 1 apply with equal force to claim 17. In addition, claim 17 provides in part, “wherein said clips are separate from said barbs and are movable independently of said barbs”. This is not disclosed or described in Edoga as explained in detail above. Edoga does not disclose a plurality of barbs. Even assuming for the sake of argument that Edoga discloses a plurality of barbs, the wire segments 134 of Edoga are disclosed as being driven out of hooked staple guides 140 and thus are not independent of the so-called “barbs”.

The claims depending from claim 17 include additional allowable subject matter and are allowable at least by virtue of their dependency from an allowable claim thus requiring no further comment at this time. Thus, it is respectfully submitted that claim 17 and the claims dependent thereon are not anticipated by Edoga. Withdrawal of the rejection is therefore proper and respectfully requested.

Independent Claim 22

The arguments above with respect to claims 1 and 17 apply with equal force to claim 22 which has been amended to provide in part, “a plurality of barbs...a plurality of clips...independent of said barbs”. As explained above, Edoga does not disclose a plurality of barbs. Furthermore, the so-called “clips”, wire segments 134, of Edoga are driven out of the so-called “barbs”, staple guides 140, and thus the two elements are not independent of one another.

The claims depending from claim 22 are allowable at least by virtue of their dependency from an allowable claim and include additional allowable subject matter. For example, claim 23 provides in part “wherein said clips comprise shape memory material, have a memory set closed configuration, and move toward said closed configuration when ejected from said support structure.” As described in connection with claim 1 above, this is not disclosed or described in Edoga. Thus, it is respectfully submitted that claim 22 and the claims dependent thereon are not anticipated by Edoga. Withdrawal of the rejection is therefore proper and respectfully requested.

Independent Claim 28

The arguments above with respect to claims 1, 17 and 22 apply with equal force to claim 28 which has been amended to provide in part, “a plurality of clips being slidably coupled to said support structure and independent of said barbs”. As explained above, Edoga does not disclose a plurality of barbs. Furthermore, the so-called “clips”, wire segments 134, of Edoga are driven out of the so-called “barbs”, staple guides 140, and thus the two elements are not independent of one another.

The claims depending from claim 28 are allowable at least by virtue of their dependency from an allowable claim and include additional allowable subject matter. For example, claim 29 provides in part “wherein said clips comprise shape memory material, have a memory set closed configuration, and move toward said closed configuration when ejected from said support structure.” As described in connection with claims 1 and 23 above, this is not disclosed or described in Edoga. Thus, it is respectfully submitted that claim 28 and the claims dependent

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thereon are not anticipated by Edoga. Withdrawal of the rejection is therefore proper and respectfully requested.

Independent Claim 33

Claim 33 provides in part, “a plurality of barbs, each coupled to said support structure and having a distal end portion...means for moving said barbs between a first position where said distal end portions are inside said support structure to a second position where said distal end portions extend from said support structure”. First, the arguments above with respect to claims 1, 17, 22 and 28 apply with equal force to claim 33. Edoga does not disclose a plurality of barbs. Furthermore, the Examiner at Page 3 of the Office Action, points to Figs. 4 and 5 of Edoga alleging that Fig. 4 discloses barb distal ends retracted into and out of a support structure. At Page 2 of the Office Action the Examiner alleges that the support structure is the tubular structure which graft 110 is attached onto. According to the disclosure of Edoga and as depicted in Figs. 4 and 5, the graft is adjacent to stapler housing filler 130. Even if stapler housing filler 130 were to be considered a support structure, Fig. 4 discloses the distal ends of the staple guides 140, the so-called “barbs”, as remaining outside of the housing filler 130.

The claims depending from claim 33 include additional allowable subject matter and are allowable at least by virtue of their dependency from an allowable claim thus requiring no further comment at this time. Thus, it is respectfully submitted that claim 33 and the claims dependent thereon are not anticipated by Edoga. Withdrawal of the rejection is therefore proper and respectfully requested.

The 35 U.S.C. § 103(a)) rejection of the claims

The Examiner rejected claims 1-33 under 35 U.S.C. § 103(a) as being unpatentable over Miller et. al. (“Miller” U.S. Patent No. 6,709,442) in view of Loshakove et. al. (“Loshakove” U.S. Patent App. No. 2004/0087985). As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

At Page 5-6 of the Office Action, the Examiner states that Miller discloses the invention substantially as claimed except for the device further includes a plurality of barbs, each barb

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being coupled to the support structure and the barbs being separate from the clips, which are ejectable from the support structure independently of the barbs. The Office Action goes on to allege that Loshakove discloses in Figs. 5A-5F an anastomosis device comprising a plurality of pullers 512 for pulling the lips of the incision of the blood vessel into a desired location relative to another lip for effecting anastomosis connection. Further, the Examiner alleges it would have been obvious to one of ordinary skill in the art to replace the pivoting arms 172 of Miller with the pullers as disclosed by Loshakove in order to improve the effectiveness and safety of Miller's device.

Independent Claim 1 provides:

Surgical connection apparatus comprising:

a support structure;

a plurality of self-closing clips, each clip being releasably coupled to said support structure; and a plurality of barbs, each barb being coupled to said support structure, said barbs being separate from said clips, which are ejectable from said support structure independently of said barbs.

Neither Miller nor Miller in combination with Loshakove disclose a plurality of self-closing clips *and* a plurality of barbs. The Examiner asserts that it would have been obvious to one of ordinary skill in the art to replace the pivoting arms of Miller with the pullers as disclosed by Loshakove. Applicants respectfully submit that this is not supported by the references themselves or by the knowledge generally available to one skilled in the art. There is no incentive to modify Miller in the manner suggested by the Examiner. Specifically, there is no reason or suggestion either in the references themselves, in the rationale presented by the Examiner or in the knowledge available to one skilled in the art to replace the arms 172 of delivery instrument 170 of Miller with the side vessel pullers 512 of Loshakove. Likewise, there is no explanation of how one would carry out the proposed modification. The delivery instrument 170 of Miller deploys graft 158 having flanges 162. The arms 172 of the tool 170 extend to support flange 162 during attachment of the graft to the aorta wall. Col. 10 lines 57-64. As is described in Miller and as is apparent from Figs. 14-16, arms 172 deploy graft flange 162 and retain the flange against the inner wall of the target vessel (the aorta wall 166) in order that

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fasteners 10 may be deployed. *See* Col. 10 line 40 – Col. 11 line 34. In contrast, Loshakove discloses target vessel pullers 512 and “in some embodiments of the invention, the insertion of pullers 512 is manual.” The pullers are retracted to pull the lips on the target vessel *into a multi-clip connector*. [0100]. Furthermore, the multi-clip connector comprises a ring having a plurality of side and end opposing clip arms. Applicants fail to see how a puller 512 could be incorporated into the device of Miller or why such a modification would be made. There is no reasonable basis to assume that the pullers of Loshakove would provide the flange deployment and retention required in Miller in order to deploy *individual* ones of said fasteners 10. Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727.

In addition, Miller does not disclose self-closing clips. The fastener 10 and suture element 236 of Miller are disclosed as coils and suture respectively and do not necessarily ‘close’ let alone “self-close”. For at least the foregoing reasons, Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

The claims depending from claim 1 include additional allowable subject matter and are allowable at least by virtue of their dependency from an allowable claim thus requiring no further comment at this time. Thus, it is respectfully submitted that claim 1 and the claims dependent thereon are not unpatentable over Miller in view of Loshakove. Withdrawal of the rejection is therefore proper and respectfully requested.

Independent Claim 17 provides:

Surgical connection apparatus comprising:

a support structure forming a first plurality of paths and a second plurality of paths;
a plurality of clips, each clip being slidably disposed in one path of said first plurality of paths; and
a plurality of barbs, each barb being slidably disposed in one path of said second plurality of paths; wherein said clips are separate from said barbs and are movable independently of said barbs.

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The arguments with respect to claim 1 apply with equal force to claim 17 and the claims dependent thereon. Miller does not disclose a plurality of barbs and a plurality of clips let alone the paths associated therewith as set forth in claim 17. Loshakove also does not disclose this combination of elements and no reason to modify Miller to include these features has been provided. Therefore, claim 17 and the claims that depend therefrom are allowable.

Independent Claim 22 provides:

Surgical connection apparatus for connecting a first structure to a second structure, said connection apparatus comprising a support structure, a plurality of barbs coupled to said support structure, a plurality of clips being slidably coupled to said support structure and independent of said barbs; means for moving said barbs; and means for ejecting said clips from said support structure.

The arguments with respect to claim 1 apply with equal force to claim 22 and the claims dependent thereon. Miller does not disclose a plurality of barbs and a plurality of clips independent of the barbs as set forth in claim 22. Loshakove also does not disclose this combination of elements and no reason to modify Miller to include these features has been provided. Therefore, claim 22 and the claims that depend therefrom are allowable.

Independent Claim 28

Surgical connection apparatus for connecting a first structure to a second structure, said connection apparatus comprising a support structure, a plurality of barbs coupled to said support structure, a plurality of clips being slidably coupled to said support structure and independent of said barbs; and means for simultaneously ejecting said plurality of clips.

The arguments with respect to claim 1 apply with equal force to claim 28 and the claims dependent thereon. Miller does not disclose a plurality of barbs and a plurality of clips independent of the barbs as set forth in claim 28. Loshakove also does not disclose this combination of elements and no reason to modify Miller to include these features has been provided. Therefore, claim 28 and the claims that depend therefrom are allowable.

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Independent Claim 31

Surgical connection apparatus for connecting a first structure to a second structure, said connection apparatus comprising a support structure, a plurality of barbs, each coupled to said support structure and having a distal end portion, a plurality of clips slidably coupled to said support structure, means for moving said barbs between a first position where said distal end portions are inside said support structure to a second position where said distal end portions extend from said support structure; and means for ejecting said clips from said support structure.

The arguments with respect to claim 1 apply with equal force to claim 31 and the claims dependent thereon. Miller does not disclose a plurality of barbs and a plurality of clips independent of the barbs as set forth in claim 31. Loshakove also does not disclose this combination of elements and no reason to modify Miller to include these features has been provided. Therefore, claim 31 and the claims that depend therefrom are allowable.

In view of the foregoing Applicants submit withdrawal of the §103(a) rejection of the claims is proper and respectfully requested.

CONCLUSION

The amendments made herein are presented solely in an effort to advance prosecution. Applicants reserve all rights to pursue any cancelled subject matter or claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claim, as required by MPEP § 821.04.

If the Examiner believes that a telephone conversation would be useful in addressing any remaining open issues in this case, the Examiner is invited to contact the undersigned at 763-505-8418.

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Please charge any required fees including fees for any required extensions of time under 37 C.F.R. §1.17 or credit any overpayment to Deposit Account No. 13-2546.

Respectfully submitted,

Date: January 29, 2009

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